K003547

DEC 21 2000

510(k) Summary

Submitter Name	Terang Nusa Sdn Bhd
Submitter Address	1, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan , Malaysia.
Submitter Telephone	+60 9 7735133
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Contact Person	LOW , Chin Guan
Date of preparation	20 Oct 2000
Trade Name	NUGARD DG, Green-Mint
Common Name	Latex Examination Glove, Green-Mint, Contain less than 100 microgram/gram of water extractable protein.
Classification	Patient Examination Glove
Legally marketed device to which substantial equivalence is being claimed.	The NUGARD DG, examination glove described in this 510(k) is substantially equivalent to the NUGARD latex examination glove that is currently marketed.
Description of device	NUGARD DG meet the requirement for examination gloves described by the American Standard for Testing and Material ASTM D3578(00), green in color , mint scented and prepowdered. Sizes available is from XS – XL

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Intended Use of the device	These examination gloves are to be worn by healthcare workers or similar personnel during work to prevent cross contamination between the user and the patient.
Summary of technological characteristics compared to marketed device	There is no variation in technological characteristics.
Brief description of non-clinical tests	Test conducted per ASTM D3578, ASTM D512 indicates that the product meet the requirements. Primary Skin irritation test ASTM F 719-81 Dermal sensitization Test ASTM F 720-81 (86) indicates no sensitization or irritation.
Brief description of clinical tests	Not carried out
Conclusion drawn from clinical and non clinical tests	Non-clinical tests and biocompatibility tests indicate device meet all performance and biocompatibility requirements.
Additional information deemed necessary by the FDA	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Mr. Chin-Guan Low
Managing Director
Terang Nusa SDN BHD
1 Jalan 8, Pengkalan Chepa 2
Industrial Zone
16100 Kota Bharu, Kelantan,
MALAYSIA

Re: K003547
Trade Name: NUGARD DG Powdered Green-Mint Latex Examination Gloves With Protein Content Labeling Claim (100 micrograms or less)
Regulatory Class: I
Product Code: LYY
Dated: November 8, 2000
Received: November 17, 2000

Dear Mr. Low:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indication for use Statement

Submitter	:	Terang Nusa Sdn Bhd
510(k) Number	:	K003547
Device Name	:	Latex Examination Glove, Green-Mint, Powdered, Contains 100 microgram or less of Water Extractable Protein
Trade Name	:	NUGARD DG

Indication for use :

These examination gloves are for use by healthcare workers or similar personnel during work to prevent cross contamination or cross infection between the user and the patient.

Concurrence of CDHR Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Dental, Infection Control,

General Hospital Devices

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Prescription Use _____ *OR* Over the counter ✓

Per 21 CFR 801.109